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10/539,138

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EXAMINER

LAU, JONATHAN S

ART UNIT

PAPER NUMBER

1623

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/539,138 | Applicant(s) TAKEUCHI ET AL. | |
| | Examiner Jonathan S. Lau | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is responsive to Applicant's amendment and remarks, filed 11 Mar 2008, in which claims 8, 9, 12-15, 17 and 40-46 have been cancelled and claims 1-5 have been amended to change to breadth and scope of the claims.

This application is the national stage entry of PCT/JP03/16047, filed 15 Dec 2003; claims benefit of foreign priority documents JAPAN 2002-368153, filed 19 Dec 2002; JAPAN 2003-62117, filed 07 Mar 2003; JAPAN 2003-86567, filed 26 Mar 2003; JAPAN 2003-163732, filed 09 Jun 2003; JAPAN 2003-349976, filed 10 Aug 2003. English language translations of the foreign priority documents are not currently of record.

Claims 1-5 are pending. Claims 8, 9, 12-15, 17 and 40-46 have been cancelled.

Objections Withdrawn

Applicant's amendment, filed 11 Mar 2008, with respect to the objections regarding the specification of the disclosure has been fully considered and found to be persuasive to remove the objection as the amendment corrects the minor informalities detailed in this objection. Therefore this objection is **withdrawn**.

Rejections Withdrawn

Applicant's amendment, filed 11 Mar 2008, with respect to the rejection of claims 1-5, 8, 9, 12-15, 17 and 40-46 under 35 U.S.C. 102(b) as being anticipated by Mandai

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et al. (US Patent 5,780,620, issued 14 Jul 1998, of record) have been fully considered and found to be persuasive to remove the rejection of claims 8, 9, 12-15, 17 and 40-46 as the amendment cancels claims 8, 9, 12-15, 17 and 40-46.

Therefore this rejection of claims 8, 9, 12-15, 17 and 40-46 is **withdrawn**.

However, this rejection of claims 1-5 is maintained as modified below.

Applicant's amendment, filed 11 Mar 2008, with respect to the rejection of claims 8 and 9 under 35 U.S.C. 102(b) as being anticipated by Kubota et al. (US Patent 5,908,767, issued 1 Jun 1999, of record) have been fully considered and found to be persuasive to remove the rejection of claims 8 and 9 as the amendment cancels claims 8 and 9.

Therefore this rejection is **withdrawn**.

Applicant's amendment, filed 11 Mar 2008, with respect to the rejection of claims 1-5, 12-15, 17 and 40-46 under 35 U.S.C. 103(a) as being unpatentable over Kubota et al. (US Patent 5,908,767, issued 1 Jun 1999, of record) have been fully considered and found to be persuasive to remove the rejection of claims 8, 9, 12-15, 17 and 40-46 as the amendment cancels claims 8, 9, 12-15, 17 and 40-46.

Therefore this rejection of claims 8, 9, 12-15, 17 and 40-46 is **withdrawn**. This rejection of claims 1-5 is maintained as modified below.

Applicant's amendment, filed 11 Mar 2008, with respect to the rejection of claims 8-9 and 12-14 on the ground of nonstatutory obviousness-type double as being unpatentable over claims 12-15 and 1-2 respectively of U.S. Patent No. 5,780,620 have been fully considered and found to be persuasive to remove the rejection because the amendment cancels claims 8-9 and 12-14.

Therefore this rejection is **withdrawn**.

The following are modified rejections necessitated by Applicant's amendment and remarks, filed 11 Mar 2008, in which claims 1-5 have been amended to change to breadth and scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Mandai et al. (US Patent 5,780,620, issued 14 Jul 1998, cited in PTO-892) as evidenced by Bell et al. (J. Agric. Food Chem. 1994, 42, p2398-2401, cited in PTO-892).

Mandai et al. disclose an alpha-glucosyl saccharide bearing a trehalose structure at its end with a glucose polymerization degree of 3 or higher (column 2, lines 38-41 and 66-67), in particular having 1, 2, 3, 4, or 5 glucose molecules and 1 trehalose

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molecules. See Mandai et al. column 11, lines 20-26. Broadly construed the trehalose is an end group of each of the glucosyl groups that are bound to the trehalose (instant claim 3), as described in column 2, lines 1-2. Mandai et al. disclose the oligosaccharide is useful for the production of food products and compositions including cosmetics and pharmaceuticals as a moisture-controlling agent. See Mandai et al. column 5, lines 29-34 and column 6, lines 58-60. The drying agent comprises at least 10% of the total weight of the moisture inhibiting agent of the non-crystalline, or amorphous, oligosaccharide powder containing multiple saccharides, for example disclosed in Example A-9 on column 19, lines 10-14. One embodiment disclosing the production of a composition wherein the trehalose derivative is incorporated in an amount of at least ten percent of the total weight of said composition on a dry solid basis is disclosed in Example B-6 on column 20, lines 25- 44, wherein 50 parts by weight of maltosyl maltoside trehalose (instant claims 1-3), in the form of an amorphous powder (instant claim 4) are combined with 33 parts by weight of dried orange juice, 10 parts by weight sucrose (instant claim 5), 0.65 parts by weight of citric anhydride, 0.1 part of malic acid, 0.1 parts by weight of L-ascorbic acid, 0.1 part by weight of sodium citrate, 0.5 parts by weight of pullulan and an appropriate amount of powdered flavoring agent to homogeneity to prepare a powdered juice composition, and wherein the product is free of undesirable moisture intake.

Mandai et al. is silent to the property of the glass-transition temperature. However, it is apparent from what is disclosed that the method of controlling or inhibiting moisture disclosed in Mandai et al., comprising the same active steps, inherently

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anticipates the method for increasing glass-transition temperature. As evidence, see Bell et al. (J. Agric. Food Chem. 1994, 42, p2398-2401, cited in PTO-892). Bell et al. provides evidence that there is an interdependence between water activity, moisture, and the glass transition (page 2399, right column, paragraph Results and Discussion. Bell et al. provides evidence that inhibiting the moisture content increases the glass-transition temperature (T_g), for example model system PVP-LMW has a T_g of -30°C at 38.4% moisture, a T_g of 18°C at 20.3% moisture, and a T_g of 42°C at 10.6% moisture (page 2400, left column, table 2). Therefore Mandai et al. inherently anticipates the instant invention as claimed.

Response to Applicant's amendment and remarks:

Applicant's amendment and remarks, filed 11 Mar 2008, have been fully considered and found not persuasive.

Applicant's amendment changes the intended use of the method of the instantly claimed invention to a method for increasing glass-transition temperature in a composition.

As detailed in the modified rejection above, it is apparent from what is disclosed that Mandai et al. inherently anticipates the instantly claimed method for increasing glass-transition temperature.

Therefore this rejection is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubota et al. (US Patent 5,908,767, issued 1 Jun 1999, of record) as evidenced by Bell et al. (J. Agric. Food Chem. 1994, 42, p2398-2401, cited in PTO-892).

Kubota et al. discloses non-reducing saccharides bearing at their ends trehalose structures with glucose polymerization degrees of 3 or higher (column 2, lines 46-49), specifically trehalose with one, two, three, four, or five glucose molecules attached (column 16, lines 37-45) (instant claim 3), which possess desirable properties of osmosis controlling ability, moisture retaining ability, and ability to prevent retrogradation of gelatinized starch. See Kubota et al. column 10, lines 15-21. Kubota et al. discloses the use of the trehalose derivative as a desiccant in food products, cosmetics,

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medicines, and materials. See Kubota et al. column 10, lines 30-34. Kubota et al. discloses the use of the trehalose derivative in combination with starch syrup powder, glucose, maltose, or sucrose. See Kubota et al. column 10, lines 45-47. Kubota et al. disclose preparations of both the crystalline trehalose derivative (see Example A-5 in column 35, lines 15-20) and an amorphous trehalose derivative in which the trehalose derivative is not crystallized (see Example A-1 in column 33, lines 23-25) in which the trehalose derivative is at least 10% of the total weight of the trehalose derivative-containing agent. Kubota et al. disclose incorporating the trehalose derivative in compositions wherein the trehalose is incorporated in an amount of at least one percent to the total weight of said composition on a dry solid basis (instant claims 1-3), for example in Example B-4 wherein three parts by weight gum base are combined with 4 parts sucrose and 3 parts by weight of a crystalline trehalose hydrate powder. See Kubota et al. column 38, lines 40-46. Kubota et al. disclose incorporating the amorphous trehalose derivative (instant claim 4) into a food composition wherein the trehalose is incorporated in an amount of at least ten percent of the total weight of said composition on a dry solid basis (instant claims 1-3), for example in Example B-2 wherein one hundred parts by weight of 55% sucrose solution (instant claims 5) was mixed with 30 parts by weight of a syrup containing non-reducing saccharides obtained by the method in Example A-1 while heating, concentrated by heating in vacuo to a moisture content lower than 2%, admixed with one part by weight of citric acid and appropriate amounts of lemon flavor and coloring agent and shaped in a conventional manner to obtain products. The products are high-quality hard candies which are crisp,

superior in taste and free of crystallization of sucrose and deformation. See Kubota et al. column 38, lines 10-20.

Kubota et al. does not specifically disclose the property of inhibiting moisture variation in a composition by incorporating the trehalose derivative into said composition.

It would have been obvious to one of ordinary skill in the art at the time of the invention that the moisture variation in the composition incorporating the trehalose derivative would be inhibited. Kubota et al. discloses that the trehalose derivative possesses the desirable properties of moisture retaining ability, and ability to prevent retrogradation of gelatinized starch. See Kubota et al. column 10, lines 15-21. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the desirable properties of moisture retaining ability, and ability to prevent retrogradation of gelatinized starch of the trehalose derivative or that these desirable properties would be inherently included in the disclosed compositions incorporating the trehalose derivative.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Kubota et al. is silent to the property of the glass-transition temperature. However, it is apparent from what is disclosed that the method of controlling or inhibiting moisture, using the trehalose derivative as a desiccant, made obvious by Kubota et al., comprising the same active steps, necessarily renders unpatentable the method for increasing glass-transition temperature. As evidence, see Bell et al. (J. Agric. Food Chem. 1994, 42, p2398-2401, cited in PTO-892). Bell et al. provides evidence that there is an interdependence between water activity, moisture, and the glass transition (page 2399, right column, paragraph Results and Discussion. Bell et al. provides evidence that inhibiting the moisture content increases the glass-transition temperature (T_g), for example model system PVP-LMW has a T_g of -30°C at 38.4% moisture, a T_g of 18°C at 20.3% moisture, and a T_g of 42°C at 10.6% moisture (page 2400, left column, table 2). Therefore method of controlling or inhibiting moisture made obvious by Kubota et al. necessarily renders the instant invention as claimed unpatentable.

Response to Applicant's amendment and remarks:

Applicant's amendment and remarks, filed 11 Mar 2008, have been fully considered and found not persuasive.

Applicant's amendment changes the intended use of the method of the instantly claimed invention to a method for increasing glass-transition temperature in a composition.

As detailed in the modified rejection above, the method of controlling or inhibiting moisture made obvious by Kubota et al. necessarily renders the instant invention as claimed unpatentable.

Therefore this rejection is **maintained**.

Conclusion

No claim is found to be allowable.

Applicant's amendment necessitated the new or modified grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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